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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/651,840	08/29/2003	Richard G. Cartledge	42749-0010	8172
25213	7590	10/30/2006	EXAMINER	
HELLER EHRMAN LLP 275 MIDDLEFIELD ROAD MENLO PARK, CA 94025-3506			POUS, NATALIE R	
			ART UNIT	PAPER NUMBER

3731

DATE MAILED: 10/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/651,840

Applicant(s)

CARTLEDGE ET AL.

Examiner

Natalie Pous

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14, 15, 18, 19 and 24 is/are rejected.
- 7) ☒ Claim(s) 13, 16, 17 and 20-23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date See Continuation Sheet.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :3/6/06, 11/26/04, 2/23/04, 1/29/04, 9/15/03.

DETAILED ACTION

Response to Arguments

Applicant's arguments, see pages 8-9, filed 8/23/06, with respect to the rejection(s) of claim(s) 1-24 under 35 USC 102 and 103. have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Spence et al. (US 6797002), see below

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-10 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 recites the limitation "said fastener" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. It is noted that dependent claim 1 recites that the implantable device is "configured to be coupled to a fastener," but does not positively claim the fastener device. Claims 7-10 and 12 are subsequently rejected as being dependent off of rejected claim 6.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites the limitation "said sutures" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 5-7, 11, 14 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by of Spence et al. (US 6797002).

Regarding Claim 1, Spence teaches an implantable device for controlling the internal circumference of an anatomic orifice or lumen, comprising:

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An implantable device (354) with a body and having an adjustable member (354d) configured to adjust the dimensions of the implantable device, the implantable device configured to be coupled to a fastener that provides fastening of said implantable device to tissue around the anatomic orifice (Column 7, proximate lines 61-66), the implantable device having a surface (354) that comes in direct contact with the anatomic orifice or lumen (334), said surface substantially defining a plane; an adjustment tool (362) configured to actuate the adjustable member (Column 11, proximate lines 3-27); and wherein the adjustment tool (362) is coupled to an interface location (360) of the adjustable member (354d), the adjustment tool is positioned in an off-plane, non-planar orientation relative to the plane defined by said surface of the implantable device (fig. 22a).

Regarding Claim 5, Spence teaches the implantable device of Claim 1, wherein said means by which said annular ring can be fastened to the tissue around an anatomic orifice or lumen comprises an outer fabric sheath (Column 4, proximate lines 50-52) covering said annular ring through which sutures can be placed to suture said implantable device to said tissue around said anatomic orifice or lumen.

Regarding Claim 6, Spence teaches the implantable device of claim 1, wherein said fastener device includes a plurality of grommets (354) spaced around the periphery of said implantable device.

Regarding Claim 7, Spence teaches the implantable device of claim 6, wherein said sutures anchor said implantable device to the tissue around said anatomic orifice or lumen (fig. 3).

Regarding Claim 11, Spence teaches the implantable device of Claim 1, wherein said adjustment member comprises corrugations (gaps between portions 354).

Regarding Claim 14, Spence teaches the implantable device of claim 1, wherein said implantable device includes a hollow tube formed into an annular shape (fabric covering), said tube having interspaced smooth and corrugated sections (correlating to gaps between portions 354 when adjusted).

Regarding Claim 24, Spence teaches the implantable device of claim 1, wherein the fastener is integrated with the implantable device (fig. 3)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spence in view of Ortiz et al. (US 6419696).

Spence teaches all limitations of preceding dependent claim 1 as previously described, but fails to teach the following:

- wherein said means by which said annular ring can be fastened to the tissue around an anatomic orifice or lumen comprises a plurality of barbs extending from said annular ring for engaging the tissue around said anatomic orifice or lumen
- wherein each of said barbs is oriented in a consistent, tangential direction with respect to the annular ring such that rotational motion of the annular ring in a first direction will engage said retention barbs with the desired tissue, and rotational motion of the annular ring in a direction opposite to said first direction will disengage said retention barbs from said desired tissue
- wherein each of said barbs further comprises a hook at its free end

Ortiz teaches an implantable device for controlling the internal circumference of an anatomic orifice or lumen, wherein said means by which said annular ring can be fastened to the tissue around an anatomic orifice or lumen comprises a plurality of barbs (44a) extending from said annular ring for engaging the tissue around said anatomic orifice or lumen, wherein each of said barbs is oriented in a consistent, tangential direction (44a, Fig. 5b) with respect to the annular ring such that rotational motion of the annular ring in a first direction will engage said retention barbs with the

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desired tissue, and rotational motion of the annular ring in a direction opposite to said first direction will disengage said retention barbs from said desired tissue, and wherein each of said barbs further comprises a hook (164) at its free end in order to facilitate additional securement to the anatomic orifice or lumen (Column 6, proximate lines 14-28). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Spence with barbs as taught by Ortiz in order to facilitate additional securement to the anatomic orifice or lumen.

Claims 15, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spence in view of Ahmadi (US 4602911). Spence teaches all limitations of preceding dependent claim 1 as previously described, and further teaches wherein the adjustment tool includes a turning device to adjust the implantable device from a remote location, and wherein said turning device is disengageable from the device after the adjustments (fig. 22a); but fails to teach wherein said adjustment member includes teeth engaged with a gear. Ahmadi teaches an implantable device having a an adjustment member including teeth engaged with a gear in order to easily and precisely adjust the size of the implant. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Spence with an adjustment member including teeth engaged with a gear in order to easily and precisely adjust the size of the implant.

Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spence in view of Gabbay (US 6368348). Spence teaches all limitations of preceding dependent claim 1, and further teaches wherein sutures anchor the implantable device

to tissue (fig. 3), Spence however fails to teach wherein a fastener device includes a plurality of grommets spaced around the device, wherein the grommets are soft, wherein the grommets include tabs, or define holes which a suture can be placed. Gabbay teaches an implantable device having a fastener device including a plurality of grommets (24) through which sutures can be placed in order to securely fasten the device to the anatomical orifice. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Spence with a suturing grommets as taught by Gabbay in order to securely fasten the device to the anatomical orifice.

Claims 1, 6, 9 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spence in view of Northrup et al. (US 2002/0128708). Spence teaches all limitations of preceding dependent claims, but fails to teach wherein the fastening device includes a plurality of grommets spaced around the periphery of said implantable device, and wherein said implantable device includes alternating sections of corrugations and grommets spaced around the periphery of the device. Northrup teaches a device for implantation into an anatomic orifice or lumen, wherein the the fastening device includes a plurality of grommets (10) having tabs including holes (24), spaced around the periphery of said implantable device, and wherein said implantable device includes alternating sections of corrugations (190) and grommets (10) spaced around the periphery of the device in order to both aid in fastening the device to the orifice or lumen, and serve as a ruler, providing the surgeon with a perimeter dimension in centimeters, according to one embodiment, of e.g. the free margin of the anterior

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mitral leaflet. Thus, intersegmental sutures 190 serve as sizing features, which can indicate the length of the anatomical structure to which apparatus 100 is being applied (paragraph 49). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Spence as taught by Northrup in order to both aid in fastening the device to the orifice or lumen, and serve as a ruler, providing the surgeon with a perimeter dimension in centimeters, according to one embodiment, of e.g. the free margin of the anterior mitral leaflet. Thus, intersegmental sutures serve as sizing features, which can indicate the length of the anatomical structure to which apparatus is being applied.

Allowable Subject Matter

Claims 13, 16-17 and 20- 23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRJ
10/26/06


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